

REMARKS

The application has been amended to place the application in condition for allowance at the time of the next Official Action.

Claims 45-47 and 49-89 are pending in the application. Claims 56 and 58-86 are withdrawn from consideration as being drawn to a non-elected species.

Claim 88 is amended to change "reservoir" to "casing" to clarify that the entirety of the external surface of the reservoir contacts an internal surface of the casing. This change is believed to address the 35 USC 112, second paragraph rejection noted in the Official Action.

Claims 45-47, 49-52, 87 and 88 are rejected as anticipated by YAMASHITA JP 55-073352. This rejection is respectfully traversed.

Claim 45 provides that the casing forms a peripheral shell surrounding an external surface of the reservoir with substantially zero clearance.

The position set forth in the Official Action is that the term "substantially" broadens the limitation of zero clearance such that the gap of YAMASHITA would have substantially zero clearance.

However, this position is believed untenable at least for the following reasons:

First, it has been held that while words such as "substantially", "approximately" and "about" broaden the term that it modifies to some degree, it cannot be allowed to negate the meaning of the word it modifies. *Arvin Industries, Inc. v. Berns Air King Corp.*, 525 F.2d 182, 188 USPQ 49, 51 (7<sup>th</sup> Cir. 1975); *Borg-Warner Corp. v. Paragon Gear Works, Inc.*, 355 F.2d 400, 148 USPQ 1, 4 (1<sup>st</sup> Cir. 1965), cert. Dismissed, 384 U.S. 935, 149 USPQ 905 (1966).

As is known in the art, words such as "substantially", "approximately" and "about" are often used in claims to prevent a potential infringer from avoiding literal infringement simply by making a minor modification.

In the present case, the word "substantially" is used to modify the term "zero clearance". The reservoir has substantially zero clearance because the reservoir is contacting or almost contacting the inner walls of the casing. This structure allows the reservoir to be made of a thin walled or weak material whereas the casing is made from a strong material.

Accordingly, the strong casing supports the relatively weak-walled reservoir from pressures exerted on the reservoir developed during injection when the semi-solid formulation is compressed (against the walls of the reservoir). See, for example, page 3, lines 30-37 of the original application. This structure of a thin walled reservoir and a relatively thick walled casing with substantially zero clearance therebetween

prevents the reservoir from rupturing or becoming deformed. See, for example page 15, lines 19-23 of the original application.

In contrast, YAMASHITA teaches a gap between the reservoir 11 and the casing 17 as shown in Figure 4 to accommodate thermal expansion and contraction. The presence of a designed in gap is contrary to the meaning of the term "zero clearance". That is, the present invention attempts to avoid a gap. Thus, using the word "substantially" to modify "zero clearance" as broadly interpreted in the Official Action would negate the meaning of the term "zero clearance". Accordingly, the gap of YAMASHITA does not have substantially zero clearance.

Moreover, the reservoir 11 of YAMASHITA is glass, which is a rigid material. Having substantially zero clearance would not allow for thermal expansion and contraction of the glass such that the glass would break against the casing if there were zero clearance.

Second, when a claim is given a broad interpretation, such interpretation must be reasonable with respect to how one of ordinary skill would interpret the terms of the claim, taking into account whatever enlightenment by way of definition or otherwise that may be afforded by applicant's specification. See MPEP 2111.

Based on the above-noted passages in applicants' specification, one of ordinary skill in the art would understand that the recited casing prevents the reservoir from damage or

deformation by there being substantially zero clearance between the reservoir and the casing such that any forces exerted on the reservoir are absorbed by the casing without causing damage to or deformation of the reservoir. The advantages of such structural relationship between casing and reservoir are not recognized by YAMASHITA.

Claim 45 also provides that the casing axially forces the hollow element against the base (of the needle) and strengthens the hollow element against radial pressures generated by the axial forces and generated by the ejection of the semi-solid formulation.

The base of the pipe 15 (needle) of YAMASHITA extends within main body 11 such that YAMASHITA does not disclose or suggest that the casing axially forces the hollow element against the base (of the needle). Rather, it appears that annular member 16 acts as an elastic member to elastically impede movement of reservoir 11, cap 13 and pipe 15 with respect to the casing.

Moreover, YAMASHITA does not teach that the casing strengthens the reservoir against radial pressure and based on the structure of YAMASHITA, the casing of YAMASHITA would not be capable of strengthening the reservoir against radial pressure because the gap would allow unwanted expansion/deformation of the reservoir.

Claim 45 further provides that the reservoir is prefilled with a semi-solid preparation.

The abstract of YAMASHITA provides that the pipe 15 forms a suction and discharge passage of the reservoir. The pipe being a suction passage for the reservoir would preclude the reservoir being prefilled. Moreover, since the cap 13 of YAMASHITA extends within the reservoir, the reservoir of YAMASHITA could not be prefilled without displacing by expelling a volume of preparation contained in the reservoir when the cap is inserted. Accordingly, one of ordinary skill in the art would not consider prefilling the reservoir of YAMASHITA because there would be enormous waste/contamination of the preparation when the cap is installed in the reservoir.

As the reference does not disclose that which is recited, the anticipation rejection should be withdrawn.

Claims 46, 47, 49-52, 87 and 88 depend from claim 45 and are also believed patentable over YAMASHITA.

Claims 45, 47, 49, 51, 52 and 87-89 are rejected as anticipated by ROOS 2,537,550. This rejection is respectfully traversed.

Claim 45 provides that a hollow element and a needle are held fastened to each other at a base (of the needle), by a casing which houses the reservoir. Accordingly, the casing holds the hollow element and needle together.

ROOS at column 2, lines 3-8 disclose that nozzle b includes a threaded extension b<sup>3</sup> adapted to receive an injection needle of any conventional type. Accordingly, the needle of ROOS

is threaded onto the end of nozzle b, not fastened to the hollow element by the casing. Contrary to the nomenclature noted in the Official Action, one of ordinary skill would not mistake nozzle b as a needle. One of ordinary skill would look to applicant's specification and/or the plain (dictionary) meaning of "needle". Applicant's specification on page 12, lines 20-21 teaches a conventional needle. Alternatively, Stedman's Medical Dictionary defines needle:

1. A slender, usually sharp-pointed instrument used for puncturing tissues, suturing, or passing a ligature around an artery.
2. A hollow, slender, sharp-pointed instrument used for injection or aspiration.

Source: The American Heritage® Stedman's Medical Dictionary

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As the nozzle of ROOS is neither slender, nor sharp-pointed nor used for puncturing, one of ordinary skill in the medicament injecting art would not offer the nozzle of ROOS as meeting the limitation of a needle.

Claim 89 includes similar limitations to claim 45 and is also believed patentable over ROOS.

As this reference does not disclose that which is recited, the anticipation rejection is not viable. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 45, 47, 49, 50 and 87-89 are rejected as anticipated by CHANOCH et al. 5,725,508. This rejection is respectfully traversed.

Claim 45 provides that a hollow element and a needle are held fastened to each other at a base (of the needle), by a casing which houses the reservoir. Accordingly, the casing holds the hollow element and needle together.

As seen in Figure 1 of CHANOCH, the needle 122 is threaded to the outside of the casing 100 at distal end 20 using mounting hub 128. CHANOCH does not disclose or suggest that a hollow element and a needle are held fastened to each other at a base (of the needle), by a casing.

Claim 45 further provides that a base of a needle comes into contact with one end of a hollow element, so that a piston comes into direct contact with the base.

As seen in Figure 7 of CHANOCH, only proximal end 124 of needle 122 is near hollow element 108. However, neither proximal end 124 nor any other part of the needle of CHANOCH are in contact with the hollow element 108. Further, hollow element 108 includes a shoulder (near 116 of Figure 7) that prevents contact of plunger 118 (piston) with the base of the needle. Thus, CHANOCH does not meet the limitation that a piston comes into direct contact with the base (of the needle) as recited.

Claim 89 provides that the needle is fixedly engaged between the reservoir and the housing. As set forth, above CHANOCH

discloses that the needle 122 is threaded to the outside of the casing 100 at distal end 20 using mounting hub 128. CHANOCH does not disclose or suggest that the needle is fixedly engaged between the reservoir and the housing and thus claim 89 is also believed patentable over CHANOCH.

Claims 45-47, 49-52 and 87-89 are rejected as anticipated by DECHELLIS et al. 4,921,486. This rejection is respectfully traversed.

Claim 45 provides that the hollow element and the needle are held fastened to each other at the base, by a casing. Claim 89 provides that the needle is fixedly engaged between the reservoir and the housing.

The needle of DECHELLIS is a retractable needle that can be stored inside the reservoir 16 for disposal. See Figure 3, for example, wherein a spring 24 is held in compression by a plurality of links 26. When the links are broken due to shearing action, the spring 24 forces the needle 18 into the reservoir body 16. Thus, the needle of DECHELLIS is neither between the reservoir and the housing nor is the needle fastened to the reservoir by the casing. Rather, the needle of DECHELLIS is connected to the reservoir by a frangible link, so that the needle can readily move into the reservoir when the link is broken.

Therefore, DECHELLIS neither meets the limitation that the needle is fixedly engaged between the reservoir and the



housing as recited in claim 89 nor the limitation that the hollow element and the needle are held fastened to each other by the casing as recited in claim 45.

As this reference does not disclose that which is recited, the anticipation rejection is not viable. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 53-55 and 57 are rejected as unpatentable over YAMASHITA in view of HIGASHIKAWA 5,704,918. This rejection is respectfully traversed.

HIGASHIKAWA is only cited for the teaching of an outer casing and two inner tubes that form a reservoir. HIGASHIKAWA does not teach or suggest what is recited in claim 45. As set forth above, YAMASHITA does not disclose or suggests what is recited in claim 45. Since claims 53-55 and 57 depend from claim 45 and further define the invention, the proposed combination of references would not render obvious 53-55 and 57.

In view of the present amendment and the foregoing remarks, it is believed that the present application has been placed in condition for allowance. Reconsideration and allowance of all claims pending in the application are respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

overpayment to Deposit Account No. 25-0120 for any additional  
fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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